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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,581	04/30/2002	Mortimer M. Civan	L-2070	1751

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/009,581	CIVAN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *94-116* is/are pending in the application.

4a) Of the above claim(s) *114* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *94-113,115 and 116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to the non-final rejection dated August 11, 2005, applicant has cancelled all the claims and presented new claims 94-116. In response, the Examiner has required an election of species. In the Applicants' response dated March 12, 2007, applicant has elected the following species:

A. NHE inhibitor	NHE-1 inhibitor
B. NHE-1 inhibitor	ethyl isopropyl amiloride
C. Na^+-K^+-$2Cl^-$ symport inhibitors	bumetanide
D. AE2 inhibitors	4,4'-diisothiocyantostilbene-2,2'-disulfonate
E. a compound selected from claim 101	mitotics

Claim 114 is withdrawn as being drawn to a nonelected NHE inhibitor.

Claims 94-113, 115 and 116 are pending in this application.

Claim Objections

Claims 94 and 108 are objected to because of the following informalities: The recitation of the treatment of individuals "in need" of the treatment of a certain condition is missing. Appropriate correction is required. A physician will typically examine many patients with various pathologies, and only some will have a particular disease requiring a particular treatment. It has been traditional in United States practice to recite the treatment of individuals "in need" of the treatment of a certain condition so as to indicate

that particular subset of patients actually in need of intervention; an alternative is to recite the treatment of an individual "suffering from" a given disease. Claims not specifying the subset of patients to be treated in this manner are generally viewed as being anticipated by any prior art method using a given agent since they read on administration to the general population and not a specified subset requiring treatment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 101 and 115-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, "precursor prostaglandins" (present claim 101) is a concept that was not present in the specification as originally filed. Applicants are advised that the issue here is not whether particular instance of a prostaglandin precursor, but rather whether the concept of other prostaglandin precursors other than latanoprost" was present in the specification as originally filed.

The specification as originally filed contains the following disclosures concerning a prostaglandin inhibitor:

(i) "another new type of drug, precursor prostaglandin compounds (e.g., latanoprost) are also in current use". (page 3, lines 27-28).

The above disclosure, however, does not provide adequate support for any prostaglandin precursor. Prostaglandin precursors include essential fatty acids, such as arachidonic acid, linoleic acid, eicosapentanoic acid and dihomogammalinoleic acid. There does not seem to adequate support in the specification for any of these prostaglandin precursors.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in his opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at § 2163 - 2163.05. In particular, while Applicant's specification as originally filed contained a specific reference to latanoprost as being one example of a prostaglandin precursor but such does not entitle Applicants to now claim all prostaglandin precursors because such represents a subgenus that was not previously set forth or one that would have been immediately envisaged by one skilled in the art from the specification as originally filed. "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996)"(emphasis added), see MPEP §

2163(I)(A). Also, "See also *In re Smith*. 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ('Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.' (emphasis added)).", see MPEP § 2163.05(II).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a "precursor prostaglandin".

Regarding claims 115 and 116, Applicant is claiming that an anion is transferred into the ciliary epithelial cells of the aqueous humor to block native chloride channels (claim 115) and that the anion comprises cyclamate (claim 116). These claims depend from claim 108 drawn to a method for regulating salt uptake or release by ciliary epithelial cells of the human eye by controlling or modulating the function of one or more antiports of the aqueous humor, a modulating amount of a pharmaceutical composition consisting essentially of an NHE inhibitor. Upon review of the instant specification for a clue as to where the cyclamate comes from, Figure 7 indicates that the voltage dependent change in current produces by selective A3 subtype adenosine agonist (IB-MECA) when most of the external chloride has been replaced by either aspartate or cyclamate. There is no indication that this IB-MECA is a NHE inhibitor, consequently

the claims lack written description. Since there is no IB-MECA present in claim 108, it is unclear to the Examiner where the cyclamate, that blocks the chloride channels, would come from.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 112 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 112, drawn to an analog of amiloride, a medicinal chemistry definition of analog is: An analog is a drug whose structure is related to that of another drug but whose chemical and biological properties may be quite different. The Examiner is unclear on the structure and or possible functions of an analog of amiloride. The specification does not make it clear exactly what an analog might be. The specification discloses numerous derivatives of amiloride on page 3. The Examiner suggests that the word analog be removed and substituted with the word derivative.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 94-96, 102 and 105-107 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cherksey U.S. Patent No. 4,950,591.

Cherksey teaches amiloride is an agent that selectively blocks ion transport and interacts with a Sodium Hydrogen Exchange inhibitor at high concentrations (column 1, lines 21-27). Amiloride and derivatives are capable of regulating membrane transport, cellular volume or cellular pressure disorders (column 2, lines 5-10). The amiloride derivatives are useful when applied topically for the treatment of glaucoma (column 3, line 66 to column 4, line 3 and column 5, lines 42-47).

Claims 94 and 102-105 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Drug Facts and Comparisons (1994).

Page 6 of Applicant's instant specification identifies beta-blockers as NHE inhibitors (see page 6, lines 23-29).

Drug Facts and Comparisons teach timolol, a beta-blocker, to be employed to reduce elevated and normal intraocular pressure with or without glaucoma (page 2287). The mechanism appears to be a reduction of aqueous production, and a slight increase in outflow facility. Regarding claims to regulating salt uptake or release by ciliary epithelial cells of the human eye by modulation of the antiports, this action is considered to be inherent. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in Ex *parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well-known

compounds or compositions. It is now well-settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)." In the instant application, Applicants' failure to distance the proffered claims from the anticipated **prophylactic** utility renders such claims anticipated by the prior inherent use. Regarding administration of the composition to the ciliary epithelial cells of the aqueous humor, there does not seem to be any description of how one would bypass administering an eyedrop to an eye to administer said compositions to the ciliary epithelial cells of the aqueous humor. A prior art reference may anticipate without disclosing a feature of the claimed invention, if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Other precedents of the court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. E.g., *In re Cruciferous*

Sprout Litig., 301 F.3d 1343, 1351 (Fed. Cir. 2002); *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("Where the result is a *necessary consequence* of what was deliberately intended, it is of no import that the article's authors did not appreciate the results."); Atlas Powder, 190 F.3d at 1348-49 ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention. An inherent structure, composition, or function is not necessarily known."). In the instant case, the unappreciated anticipation also does not require recognition. Applicant claims to have discovered the method of modulating aqueous secretion by modulating the antiports of the aqueous humor. Since the pharmaceutical compositions claimed by applicant produced the claimed modulation of aqueous secretion, the discovery of the modulation of the antiport is inherent. In the context of the accidental anticipation, beta-blockers, such as timolol, do not accidentally modulate the antiport when the pharmaceutical composition is applied to a patient in need of treatment. The antiport necessarily and inevitably is modulated when the beta-blocker is applied and does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 94-96, 99-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adorante et al. U.S. Patent No. 5,559,151 and Cherksey U.S. Patent No. 4,950,591.

Adorante et al. teach pharmaceutical compositions and methods for treating glaucoma and/or ocular hypertension comprising administering to the mammalian eye an agent such as 4,4'-diisothiocyantostilbene-2,2'-disulfonate (DIDS) (see column 5, lines 10-18). It is noted that Adorante et al. identifies this agent as a chloride channel blocker. The identification of the agent DIDS as a chloride channel blocker does not

detract from the teaching that this agent, when it is administered to the mammalian eye, treats ocular hypertension/glaucoma because the chloride-dependent ion flux pathways will inhibit aqueous humor formation and thus, lower intraocular pressure (IOP) (column 5, lines 45-49). Adorante further teaches that drugs currently utilized in the treatment of glaucoma include, *inter alia*, miotics, sympathomimetics, beta blockers, alpha-2-agonists and carbonic anhydrase inhibitors. In vitro (see example, column 5) and in vivo (see claim 1) use are clearly disclosed.

Adorante et al. fails to teach coadministration of NHE/NHE-1 inhibitors.

Cherksey teaches amiloride (NHE inhibitor/NHE-1 inhibitor) is an agent that selectively blocks ion transport and interacts with a Sodium Hydrogen Exchange inhibitor at high concentrations (column 1, lines 21-27). Amiloride and derivatives are capable of regulating membrane transport, cellular volume or cellular pressure disorders (column 2, lines 5-10). The amiloride derivatives are useful when applied topically for the treatment of glaucoma (column 3, line 66 to column 4, line 3 and column 5, lines 42-47).

As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

It would have been made obvious to one of ordinary skill in art at the time it was made to employ two agents well-known to treat glaucoma/ocular hypertension together to treat the very same condition. Adorante et al. teach that DIDS treats glaucoma and/or ocular hypertension by inhibiting aqueous humor formation and thus, lowering IOP. Cherksey teaches amiloride (NHE inhibitor/NHE-1 inhibitor) is an agent that selectively blocks ion transport and interacts with a Sodium Hydrogen Exchange inhibitor at high concentrations (column 1, lines 21-27). Amiloride and derivatives are capable of regulating membrane transport, cellular volume or cellular pressure disorders. One would have been motivated to combine these treatments motivated by the reasoned expectation of producing a composition, which is effective in comprehensively treating persons suffering from elevated intraocular pressure and glaucoma.

Regarding claims drawn to regulating salt uptake or release by ciliary epithelial cells of the human eye or eye of an animal having a trabecular meshwork (network) by controlling or modulating the function of one or more antiports of the aqueous humor ciliary epithelial cells by administering to the ciliary epithelial cells of the aqueous humor a modulating amount of a pharmaceutical composition consisting essentially of an NHE inhibitor, Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently

possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

Claims 94-98, 102-113 rejected under 35 U.S.C. 103(a) as being unpatentable over Brandt et al. U.S. Patent No. 5,585,401 and Cherksey U.S. Patent No. 4,950,591.

Brandt et al. teach the administration of compounds that inhibit the function of Na^{+}-K^{+}-$2Cl^{-2}$ cotransporter mechanism (symport) (see abstract) such as bumetanide for topical administration (column 6, lines 30-43). It has been discovered that the trabecular meshwork of the mammalian eye regulate cell volume and fluid transport by means of the Na^{+}-K^{+}-$2Cl^{-2}$ cotransporter mechanism. Compounds that substantially inhibit operation of this mechanism also increase the outflow of the ocular fluids, thus

lowering intraocular pressure for treatment of ocular hypertension and glaucoma (column 6, lines 15-29).

Brandt et al. fails to teach coadministration of NHE/NHE-1 inhibitors.

Cherksey teaches amiloride (NHE inhibitor/NHE-1 inhibitor) is an agent that selectively blocks ion transport and interacts with a Sodium Hydrogen Exchange inhibitor at high concentrations (column 1, lines 21-27). Amiloride and derivatives are capable of regulating membrane transport, cellular volume or cellular pressure disorders (column 2, lines 5-10). The amiloride derivatives are useful when applied topically for the treatment of glaucoma (column 3, line 66 to column 4, line 3 and column 5, lines 42-47).

As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

It would have been made obvious to one of ordinary skill in art at the time it was made to employ two agents well-known to treat glaucoma/ocular hypertension together to treat the very same condition. Adorante et al. teach that DIDS treats glaucoma and/or ocular hypertension by inhibiting aqueous humor formation and thus, lowering IOP. Cherksey teaches amiloride (NHE inhibitor/NHE-1 inhibitor) is an agent that selectively blocks ion transport and interacts with a Sodium Hydrogen Exchange inhibitor at high

concentrations (column 1, lines 21-27). Amiloride and derivatives are capable of regulating membrane transport, cellular volume or cellular pressure disorders. One would have been motivated to combine these treatments motivated by the reasoned expectation of producing a composition which is effective in comprehensively treating persons suffering from elevated intraocular pressure and glaucoma. Regarding administration of the composition to the ciliary epithelial cells of the aqueous humor, there does not seem to be any description of how one would bypass administering an eyedrop to an eye to administer said compositions to the ciliary epithelial cells of the aqueous humor. A prior art reference may anticipate without disclosing a feature of the claimed invention, if that missing characteristic is necessarily present, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Regarding claims drawn to regulating salt uptake or release by ciliary epithelial cells of the human eye or eye of an animal having a trabecular meshwork (network) by controlling or modulating the function of one or more antiports of the aqueous humor ciliary epithelial cells by administering to the ciliary epithelial cells of the aqueous humor a modulating amount of a pharmaceutical composition consisting essentially of an NHE inhibitor, Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently

possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Declaration

The Declaration under 37 CFR 1.132 filed November 10, 2005 is insufficient to overcome the rejection of claims 94-116 based upon the above rejection and the rejection of claims 1, 38-41, 44-55, 68, 92 and 93 as set forth in the Office action dated August 11, 2005 because: applicant claims that the class of molecules designated as

NHE inhibitors did not include timolol or any other beta blocker at the time of the invention. In response, the applicant identifies NHE inhibitors to include beta blockers and in particular, timolol in the instant specification. A prior art reference may anticipate without disclosing a feature of the claimed invention, if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Beta blockers have been used for relief of intraocular pressure since at least 1980 (see Shell et al. U.S. Patent No. 4,281,654). The mere fact that they are not identified as NHE inhibitors does not detract from their actions of lowering intraocular pressure. Other precedents of the court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. E.g., *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002); *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("Where the result is a *necessary consequence* of what was deliberately intended, it is of no import that the article's authors did not appreciate the results."); Atlas Powder, 190 F.3d at 1348-49 ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention. An inherent structure, composition, or function is not necessarily known."). In the instant case, the unappreciated anticipation also does not require recognition. Applicants' allegation that claim 94 does not embrace timolol or any other beta blockers is incorrect. Claim 94 is drawn to regulating intraocular pressure with a composition comprising at least one sodium-hydrogen exchanger (NHE) inhibitor. When the examiner looks to the instant specification to

identify what applicant means by NHE inhibitors, Page 6 of Applicant's instant specification identifies NHE inhibitors as beta-blockers (see at least page 6, lines 23-29). Therefore, the scope of the declaration is not commensurate with the scope of the claim(s).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

June 27, 2007

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER